Decision Memo for Acupuncture for Fibromyalgia (CAG-00174N)

Decision Summary

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Decision Memo

This decision memorandum does not constitute a national coverage determination (NCD). It states CMS's intent to issue an NCD. Prior to any new or modified policy taking effect, CMS must first issue a manual instruction giving specific directions to our claims-processing contractors. That manual issuance, which includes an effective date, is the NCD. If appropriate, the Agency must also change billing and claims processing systems and issue related instructions to allow for payment. The NCD will be published in the Medicare Coverage Issues Manual. Policy changes become effective as of the date listed in the transmittal that announces the Coverage Issues Manual revision.

To: Administrative File CAG: #00174N
Acupuncture for the Treatment of Fibromyalgia

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Subject: Coverage Decision Memorandum for Acupuncture for Fibromyalgia

Date: October 10, 2003

I. Decision

CMS has determined that the evidence is not adequate to conclude that the use of acupuncture is reasonable and necessary for the treatment of fibromyalgia and, therefore, CMS will continue its noncoverage policy for acupuncture.

II. Background

On December 2, 2002, CMS began a national coverage determination process for acupuncture for fibromyalgia.

Fibromyalgia is a syndrome characterized by widespread musculoskeletal pain and soft tissue tenderness that are often accompanied by chronic fatigue and sleep disturbance. Fibromyalgia affects as many as 8-10 million persons in the U.S. and is predominantly a disorder of young and middle-aged women. Approximately 10% of fibromyalgia patients are men.

There is no confirmatory laboratory or radiological test to diagnose fibromyalgia. Its cause is unknown. Substantial overlap, however, has been noted with other unexplained conditions. For example, fibromyalgia patients frequently display other illnesses such as migraine, irritable bowel syndrome, major depression and panic disorder.[1,2] The presence of another of these clinical disorders does not exclude the diagnosis of fibromyalgia.[3] According to the American College of Rheumatology (ACR), patients are said to have fibromyalgia if both of the following classification criteria based on Wolfe, *et al.* (1999) are satisfied:

1. History of widespread pain present for at least 3 months. By definition, pain is considered widespread when pain is present in both the left and right sides of the body, as well as both above and below the waist. In addition, axial skeletal pain in the cervical spine, anterior chest, thoracic spine or low back must be present.
2. Pain in 11 of 18 tender point sites on physical examination, where the physician's digital palpation of the patient is performed with an approximate force of 4 kg. "Tender" is not to be considered "painful", and for a tender point to be considered positive, the patient must state that the palpation was painful. By definition, pain on palpation must be present in at least 11 of the following 18 bilateral sites:
    - Occiput at the suboccipital muscle insertions;
    - Low cervical at the anterior aspects of intertransverse spaces at C5-C7;
    - Trapezius at the midpoint of the upper border;
    - Supraspinatus at the origins above the scapula spine near the medial border;
    - Second rib at 2nd costochondral junctions lateral to junction upper surfaces;
    - Lateral epicondyle at 2 cm distal to the epicondyles;
    - Gluteal in upper outer quadrants of buttocks in anterior fold of muscle;
    - Greater trochanter posterior to the trochanteric prominence; or
    - Knee at the medial fat pad proximal to the joint line.[4]

No uniformly effective treatment has been established for fibromyalgia. While antidepressants are the mainstay of pharmacological treatment, a large number of traditional and nontraditional therapies have been suggested. In addition to acupuncture, the range of treatments for fibromyalgia includes patient education, low-level aerobic exercise, local corticosteroid injections of tender points, low frequency transcutaneous electrical nerve stimulation (TENS), cognitive-behavioral treatment, chiropractic manipulation, physical therapy, hypnotherapy, nutritional supplements, pain management and multidisciplinary approaches.[5]

While there is a diversity of theoretical models and techniques that are all described as acupuncture, all models and forms seek to treat and prevent symptoms and conditions through either: 1) the insertion of needles or “needling” at specifically chosen points on the body, or 2) other “non-needling” techniques focused on these points. Traditional Chinese medicine (TCM) theorizes that there are more than 2000 acupuncture points connecting 12 main and 8 secondary pathways called meridians. TCM practitioners theorize that these points connect with energy (*qi*) conducting meridians that affect the spiritual, emotional, mental and physical balance of the opposing forces of yin and yang. TCM practices are intended to improve the flow of *qi* and treatment approaches may include herbal preparations and lifestyle or dietary advice in addition to traditional Chinese acupuncture individualized to each patient’s signs and symptoms.

Modern acupuncturists or medical acupuncturists (terminology sometimes used interchangeably) do not necessarily adhere to TCM theories to support their practices. Some acupuncturists and scientists have recognized that it is difficult to identify an empirical basis for TCM’s theories concerning energy conducting meridians and have instead theorized that needling may enhance or inhibit nerve conduction. The diversity of terminology and complexity of explanatory models has thus resulted in considerable variation in acupuncture techniques.

Variations to traditional Chinese acupuncture include shallow needling, intradermal needling or intramuscular needling with or without *de qi*.[6] Acupuncturists may additionally seek a sensation of tenseness or dragging to the needles obtained by twirling, plucking or thrusting of acupuncture needles. There are also numerous variations of manually or electrically stimulated “needling” techniques, as well as multiple “non-needling” acupuncture techniques.[7]

Summarizing the current status and central issues in credentialing acupuncturists and other complementary and alternative medicine (CAM) providers, Eisenberg, *et al.* (2002) noted that: “Acupuncture, first licensed by Nevada, Oregon, and Maryland in 1973, currently is licensed in 42 states and the District of Columbia. More than 14,000 practitioners are licensed in the United States, and an additional estimated 3000 medical doctors have studied formally and incorporate acupuncture into their practices. Of the more than 70 schools of acupuncture in the United States, 37 are accredited by and 9 are in candidacy status with the U.S. Department of Education recognized Accreditation Commission for Acupuncture and Oriental Medicine (ACAOM). About one third of the states that license non-physician acupuncturists require graduation from an ACAOM school or one with an equivalent curriculum. In addition, approximately one third of licensing states require the study of biomedical sciences, including anatomy, physiology, and pathology. The National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) offers separate certification programs in Acupuncture, Chinese Herbology, and Oriental Bodywork Therapy. As with chiropractic, almost all states licensing acupuncturists require passage of a national written examination offered by NCCAOM. Twelve states also require passage of the NCCAOM practical examination.”[8]

“Credentialing problems persist. First, state requirements to practice acupuncture vary. In many states, acupuncture training requirements for medical doctors, dentists, and other allopathic providers are minimal or nonexistent. Some states permit licensed CAM providers, such as chiropractors, to practice acupuncture (with varying levels of training) whereas other states prohibit it. Second, states vary in their defined scope of practice for acupuncture and Oriental medicine…. Third, only 14 states have an independent board of acupuncture or Oriental medicine; in other states, acupuncturists are under the board of medical examiners or regulated by the departments of commerce or health…. [Fourth], approximately one quarter of the states licensing acupuncturists require prior referral from, diagnosis by, or collaboration with a licensed medical doctor.”[9]

The American Board of Medical Specialties (ABMS) is the most widely recognized U.S. organization of 24 approved medical specialty boards. ABMS certification of physicians is intended to provide assurance to the public that those certified by member boards have successfully completed an approved training program and an evaluation process assessing their ability to provide quality patient care in their specialty. No medical specialty board for acupuncture or medical subspecialties with approved certificates for acupuncture are recognized or approved by the ABMS, and no physicians have been certified by the ABMS to perform acupuncture.[10] The American Board of Medical Acupuncture, which was independently established by the American Academy of Medical Acupuncture on April 26, 2000, is not a member specialty, medical subspecialty, approved member board or associate member of the ABMS. This lack of uniformity in credentialing creates additional issues with respect to what constitutes an acupuncturist and therefore what constitutes an acupuncture procedure.

III. History of Medicare Noncoverage for Acupuncture

CMS issued a national noncoverage determination for acupuncture in the Medicare Coverage Issues Manual (CIM) May 1980, Section 35-8 (Acupuncture – Not Covered).

CMS’s Center for Medicare Management (CMM) has determined that acupuncture could potentially fall within the benefit category set forth in section 1861(b)(3) (inpatient hospital services), 1861(s)(1) (physician services), 1861(s)(2)(A) (services “incident to” a physician’s professional service of the kind that are commonly furnished in a physician’s office) or 1861(s)(2)(B) (hospital services “incident to” physicians’ services rendered to outpatients) of the statute.

IV. Timeline of Recent Activities

September 30, 2002	Mr. Jay Silverman, a beneficiary from Leesburg, Florida, submitted a letter requesting that CMS reconsider its noncoverage of acupuncture.

December 2, 2002	CMS staff worked with requestor to complete formal request, including gathering appropriate evidence, and formally accepted request for review of acupuncture for fibromyalgia.
September 4, 2002	Referred to the Agency for Healthcare Research and Quality (AHRQ) for a technology assessment on the broad topic of acupuncture. This request was refined when the formal request for specific indications was received.
June 10, 2003	Acupuncture for Fibromyalgia Technology Assessment received from AHRQ.

V. Food and Drug Administration (FDA) Status

Since 1973, the FDA has considered acupuncture devices, including needles, as investigational medical devices. In March 1996, the FDA announced that acupuncture needles had been reclassified from Class III (experimental) medical devices to Class II (non-experimental but regulated) medical devices for general acupuncture use by licensed registered or certified practitioners. Class II devices involve less stringent controls such as good manufacturing procedures and proper labeling, but data demonstrating clinical effectiveness is not required for these devices. At the time of the 1996 reclassification, no scientifically convincing data had been presented to FDA demonstrating efficacy for any acupuncture device for any medical indication.

The FDA defined an acupuncture needle as a device intended to pierce the skin in the practice of acupuncture, and that the device consists of a solid, stainless steel needle which may have a handle attached to facilitate the delivery of acupuncture treatment. The FDA requires manufacturers of acupuncture needles to label them for single use only. Acupuncture needles must also bear a prescription labeling statement which restricts their use to qualified practitioners as determined by the states, and manufacturers must provide information about device material biocompatibility and sterility.[11,12] Any other use would be an off-label use.

CMS assesses relevant health outcomes, above and beyond the safety and effectiveness regulatory mandate of the FDA. Although a device must receive FDA approval or clearance for at least one indication to be eligible for Medicare coverage, except for a category B device under an investigational device exemption (IDE) clinical trial (60 FR 48417, September 19, 1995), FDA approval/clearance alone does not entitle that device to coverage. The device must fall under a Medicare benefit category and be determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be covered by CMS. CMS has the authority to conduct a separate assessment of a device's appropriateness for Medicare coverage, including whether it is reasonable and necessary specifically for its intended use for Medicare beneficiaries (*see e.g.*, 60 FR 48417, 48420 (September 19, 1995). Under a premarket approval application (PMA) review, the FDA determines whether or not there is reasonable assurance of safety and effectiveness for the device's intended use that is stated in its proposed labeling. Medicare NCDs consider the medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. CMS determines whether or not the intervention improves net health outcomes in the Medicare population at least as well as established treatments. Thus, FDA PMA approval by itself is not sufficient for making a determination concerning Medicare coverage.

As we similarly stated in 66 FR 58788, 58797 (November 23, 2001) with regard to FDA 510(k) clearance, "[t]he criteria the FDA uses in making determinations related to substantial equivalency under section 510(k) of the Food, Drug, and Cosmetic Act is significantly different from the scientific evidence we consider in making "reasonable and necessary" determinations under Medicare. FDA does not necessarily require clinical data or outcomes studies in making a determination of substantial equivalency for the purpose of device approval under section 510(k) of the Food, Drug, and Cosmetic Act. Medicare NCDs consider medical benefit and clinical utility of an item or service in determining whether the item or service is considered reasonable and necessary under the Medicare program. Thus, a substantial equivalency approval under section 510(k) of FDA is not sufficient for making determination concerning Medicare coverage."

VI. General Methodological Principles

When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of reasonable and necessary. The evidence may consist of external technology assessments, internal review of published and un-published studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) specific clinical questions relevant to the coverage request can be answered conclusively; and 2) the extent to which we are confident that the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies

- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. The goal of our determination process is to assess net health outcomes, and we are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

CMS determines whether an intervention is reasonable and necessary by evaluating its risks and benefits. For all determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

4. Specific Methodological Issues in Acupuncture Research

Under "Issues in Acupuncture Treatment and Research," the 2002 Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment of Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)[13] **discussed three critical study design issues that aided in framing CMS's subsequent evidence analysis:**

- Selection of credible control groups
- Complexities and variability of acupuncture treatments

- Overall study design and assessment of methodological quality.

Selection of Credible Control Groups

The selection of appropriate control groups poses a challenge for all acupuncture research and is relevant to evaluate any relief of pain and soft tissue tenderness that may be associated with acupuncture for fibromyalgia. Controls can range from placebo or sham procedure controls, to standard care or no treatment at all. The use of placebo or sham versus standard care or no treatment, as well as the effects of sham procedures on outcomes, are issues of debate in the acupuncture literature. Compared to non-placebo controls who know they are not receiving treatment, placebo controls enable blinding and can potentially decrease a study's dropout rate. A placebo needle has been developed, which mimics visual and tactile sensations of acupuncture, but which disappears into the handle and does not break the skin. Sham laser acupuncture has also been utilized, which uses visual and acoustic signals similar to those found during active laser acupuncture. Additional placebo or sham procedures include use of non-traditional acupuncture points, superficial puncturing of the skin without stimulation, introduction of a sensation without puncturing in acupressure, and stimulators without connector cables in electroacupuncture.

Overall, these placebo or sham procedure controls have the potential to increase patient's perception of receiving real acupuncture and also enable double blinding. However, the most commonly used sham procedure control is needling done at theoretically irrelevant sites. While initially thought that acupuncture at these sites would have no effect, some believe that inserting a needle anywhere in the body or applying pressure to any site evokes a response. Evocation of this response can also be found with the other above-mentioned placebo controls.

Complexities and Variability of Acupuncture Treatments

Since acupuncture includes a diverse range of philosophies and treatment styles, the most accurate determination of acupuncture's effectiveness should include the evaluation of each well-defined approach, rather than evaluating an entire family of treatments as a single approach. However, many types and variations of traditional Chinese medicine (TCM) acupuncture are often combined and compared in systematic reviews. For example, while manual and electrical stimulation are seldom compared, acupressure and electroacupuncture have nonetheless been considered the same in many systematic reviews. Multiple acupuncture styles are also utilized. Ear acupuncture is perhaps the most widely used, although other systems such as scalp, hand, foot, nose and abdominal acupuncture are also considered specialties. TCM and formula acupuncture represent two different styles, but these are also often grouped together in reviews. TCM focuses on a balanced system and uses point selection based on symptoms, pulse and tongue diagnoses. The choice of points used in TCM may vary from day to day as the balance of energy (*qi*) shifts. The formula or standardized approach uses the same prescription of points for each patient. While better suited for research, this approach may not reflect actual community practice. In many ways, individualized acupuncture diagnosis and treatment is similar to psychotherapy or physiotherapy, where the therapist's skill, contact and bond with the patient may be as important in producing an effect as the treatment strategies themselves. In such settings, acupuncture therapy is adjusted according to subtle shifts, as they occur, rather than continuing with a standard acupuncture approach.

There is also variability in the technique of needle insertion and manipulation, which may influence effectiveness but is often not recorded. Diameter, length, depth of insertion, duration of retention, number of needles per treatment, temperature of needles, number of treatments and needle composition may likewise influence the outcome. Low levels of agreement have also been reported for expert acupuncturists independently evaluating the adequacy, choice and relevance of acupuncture points utilized in clinical studies.

Overall Study Design and Assessment of Methodological Quality

Many primary studies and some systematic reviews lack either a strong research design and/or an adequate description of study design on which results can be evaluated and compared. Small sample size (whether relative to the anticipated magnitude of effect and allowable standard error or absolute, such as less than 10 patients in each treatment arm) has led to under-powering of results. Some reviews report positive correlations between low methodological study quality and positive outcomes.

VII. Evidence

A. Introduction

The following summary represents the body of evidence for this decision memorandum. The evidence reviewed about the use of acupuncture for the treatment of patients with fibromyalgia includes the peer-reviewed literature evaluated by both external and internal technology assessments and expert opinion.

The sole health outcome of interest to CMS in this decision memorandum is the impact of acupuncture on pain reduction in patients with fibromyalgia.

Pain relief can be measured on a visual analog scale (VAS). A VAS asks the patient to rate his or her experience of pain severity on a 1 to 100 mm scale. This scale is not specific to acupuncture treatments but has proven validity and reliability.[14]

To assess a study's methodological quality, four of five criteria in the Jadad scale deal with randomization and blinding. The Jadad method (maximum score = 5) awards one point for a study's description of its randomization, double blinding and withdrawals and/or dropouts, and awards or deducts one point dependent upon a study's appropriate or inappropriate description of its randomization and double blinding methods.[15]

B. Discussion of evidence reviewed

1. Specific Decision Memorandum Question

CMS's evidence summary and analysis focuses on the following question: "Is there evidence of adequate methodological quality to conclude that the use of acupuncture significantly and reliably reduces pain in Medicare patients with fibromyalgia?"

2. External Technology Assessment

Assisting CMS in the initial search of the literature, AHRQ identified the following two methodologically sound technology assessments:

- United Kingdom National Health Service (NHS) Center for Reviews and Dissemination: Effective Health Care on Acupuncture (2001)[16]
- Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment of Acupuncture: Evidence from Systematic Reviews and Meta-analyses (2002)[17]

AHRQ subsequently performed a technology assessment (TA) to search for additional randomized controlled trials (RCTs) and reviews of acupuncture for fibromyalgia performed since the 2001 NHS and 2002 AHFMR publications. AHRQ reviewed the abstracts of all RCTs identified and searched for ongoing acupuncture for fibromyalgia clinical trials.

The 2001 NHS report evaluated acupuncture for chronic pain, including fibromyalgia, and was based predominantly on a review of systematic reviews conducted by the Complementary Medicine Field of the Cochrane Collaboration. Included were clinical trials of acupuncture. The NHS reviewed all systematic reviews on acupuncture from 1989 to July 2000. There were no language restrictions. In 2001 a second search was conducted to find any new reviews and RCTs. Where no systematic review was available, all RCTs on that topic were included.

The 2002 AHFMR report evaluated acupuncture for the treatment of fibromyalgia and also discussed general methodological issues in acupuncture treatment and research. This assessment is based predominantly on a review of systematic reviews and meta-analyses on acupuncture. Included were clinical trials of acupuncture or related methods such as electroacupuncture or acupressure. The AHFMR assessment reviewed all systematic reviews on acupuncture published in English between 1990 and 2001. Primary studies published since the reviews were not included.

Detailed descriptions of the NHS review's methodology, the AHFMR assessment's methodology and AHRQ's complete search strategy used to identify all studies listed are provided in Appendices B, C and D of the AHRQ TA.

The 2001 NHS and 2002 AHFMR reports cited only a single systematic review on fibromyalgia by Berman and colleagues.[18] Berman's review is the basis for all other reviews of acupuncture for fibromyalgia and included only a single English language RCT published in 1992 by Deluze, *et al.*[19] Deluze and colleagues studied 70 patients with electroacupuncture compared to sham needling. Deluze found statistically significant improvements on several outcome measures, such as pain relief, but did not follow patients beyond the three-week study period.

The 2001 NHS report criticized the literature based on three points: 1) the quality of the studies was related to study outcomes and lower quality studies were more likely to favor acupuncture; 2) most RCTs of acupuncture in chronic pain have few patients and may be underpowered; and 3) active acupuncture and sham techniques may be inadequate, including too few numbers of points, too few treatment sessions, and placement of sham needles in the same body segment as the active needles.

The 2002 AHFMR report criticized the Berman systematic review because it failed to identify the style of acupuncture (i.e., whether the points were individualized to the patient or chosen based on a formula), the appropriateness of treatment or the qualification of the practitioner.

In order to find more recent literature, AHRQ additionally searched for reviews or RCTs published since 2000. Two reviews by Berman[20] and Bandolier[21] were identified which did not include any new RCTs.

AHRQ summarized that the Deluze, *et al*. RCT used electroacupuncture rather than traditional needling technique and that none of the reviews concluded that the evidence was sufficient to use acupuncture as a first line treatment. AHRQ further noted that Deluze's three-week study was not long enough to draw conclusions about acupuncture's impact on health outcomes for patients with chronic fibromyalgia. In conclusion, AHRQ felt that longer-term studies are necessary to determine the benefit of any treatment for fibromyalgia and that there is insufficient evidence to conclude that acupuncture has efficacy for the treatment of fibromyalgia. AHRQ's complete TA of Acupuncture for Fibromyalgia can be accessed via its hyperlink on CMS's tracking sheet for this issue at http://www.cms.hhs.gov/mcd/viewtrackingsheet.asp?id=83

3. Internal Technology Assessment

Literature Search

One English language RCT by Deluze, *et al.* (1992) and several ongoing clinical trials were referenced by the requestor regarding the use of acupuncture for fibromyalgia. Following AHRQ's initial literature search, CMS itself extensively searched PubMed (1990 to present) for new RCTs and systematic reviews evaluating the use of acupuncture for fibromyalgia. CMS likewise searched the Cochrane Collaboration, the NHS Centre for Reviews and Dissemination, and the INAHTA databases for all systematic reviews and technology assessments. Keywords used in CMS's search were "acupuncture" and "fibromyalgia." RCTs must have presented original data, included greater than or equal to 10 patients, examined health outcomes, and been published as full-length articles in peer-reviewed, English language journals. Uncontrolled studies and abstracts were excluded.

Summary of Evidence

Searching all databases using the aforementioned search strategy, CMS identified no English language RCT of acupuncture for fibromyalgia other than Deluze, *et al.* (1992). Methods and results from this RCT are detailed in our "Synthesis of Evidence" section.

CMS did, however, identify one recent systematic review not discussed in AHRQ's TA. Sim and Adams (2002) reviewed 25 RCTs investigating nonpharmacological interventions for fibromyalgia, which included Deluze, *et al.*'s (1992) acupuncture study. The strengths and weaknesses of Deluze's RCT, as evaluated by CMS staff and all reviewers (including Sim and Adams), are summarized in our "CMS Analysis" section.

Synthesis of Evidence

The sole health outcome of interest to CMS in this decision memorandum is the impact of acupuncture on pain reduction. The only RCT which addressed the impact of acupuncture on pain reduction in patients with fibromyalgia was published by Deluze, *et al*. (1992). Deluze's group randomized 70 patients, comprised of 54 women and 16 men who were diagnosed with fibromyalgia defined by ACR criteria, to either real electroacupuncture or sham needling. All patients continued their other usual co-interventions and/or treatments, which included pain medications, anti-inflammatory medications, anti-depressant medications and physical therapy. The study did not include either a standard medical therapy or a no treatment control group.[22]

Mean age was 46.8 years (ranging from 42 – 51 years) in the real electroacupuncture group and 49 years (ranging from 44-53 ears) in the sham procedure group. A significantly greater number of men (p = .015) were in the sham procedure group. Treatment consisted of 6 sessions of real or sham electroacupuncture over 3 weeks. Four common acupuncture points were used in the real electroacupuncture group, as well as up to 6 other sites chosen by the acupuncturist. In the sham procedure, a similar number of needles were used but were placed about 20 mm away from the point which would have been chosen for real electroacupuncture. The electrical current used in the sham procedure was "similar to but weaker than" that used for real electroacupuncture.

A single evaluating physician was blinded to each patient's treatment group. Primary outcome measures included: 1) the patient's pain threshold; 2) number of analgesic (pain relieving) tablets used; 3) regional pain score; 4) pain recorded on visual analog scale (VAS); 5) sleep quality; 6) morning stiffness; 7) patient's appreciation of general state; and 8) the treating physician's evaluation of the patient's general state.

Deluze, *et al.* (1992) reported that patients in the real electroacupuncture group (N = 28) significantly improved post-treatment (with variable p values < .05) in each outcome measure except morning stiffness. There was no significant change pre-treatment versus post-treatment in the sham procedure group (N = 27). Post-treatment values were significantly improved (with variable p values < .05) for 5 of the 8 outcome measures in the real electroacupuncture group versus the sham procedure group. The 3 outcome measures exhibiting no significant change between the real and sham electroacupuncture groups pre-treatment and post-treatment were the number of analgesic tablets used during the prior week, the patients' regional pain score and the patients' sleep quality.

Fifteen of 70 patients withdrew from Deluze's study (8 from the real electroacupuncture and 7 from the sham procedure group) and were not re-evaluated. Of the 8 patients who withdrew from the real electroacupuncture group, 6 withdrew for reasons associated with the procedure (increase in symptoms in 2 patients, unpleasantness of needle insertion in 3 patients and ankle edema in 1 patient), 1 patient did not return, and 1 patient was hospitalized for an unrelated condition. Of the 7 patients who withdrew from the sham electroacupuncture group, 5 withdrew for reasons associated with the procedure (increase in symptoms in 4 patients and unpleasantness of needle insertion in 1 patient) and 2 patients were hospitalized for other conditions. There was no intention-to-treat analysis.

4. Medicare Coverage Advisory Committee (MCAC)

This issue was not referred to the MCAC.

5. Evidence-Based Guidelines

CMS identified no evidence-based guidelines for the use of acupuncture for the treatment of fibromyalgia.

6. Professional Society Position Statements

CMS received no formal position statements or professional society guidelines regarding the use of acupuncture for the treatment of fibromyalgia.

7. Expert Opinion

CMS received three letters from individual physicians with an interest in the coverage decision(s) for acupuncture:

- A letter from a diplomat of the American Board of Medical Acupuncture stating: "…My experience with both of these conditions [fibromyalgia and osteoarthritis] is that, while acupuncture cannot cure either condition, it may cause significant improvement in the symptoms if used on a regular basis."
- In another letter from the Vice President of Clinical Operations and MD at a community Medical Center: "… I have also utilized acupuncture for fibromyalgia patients. The results have been mixed with the younger population having greater benefits than the Medicare group…"
- From a licensed acupuncturist and MD we received a letter stating: "…There is ample evidence in the literature that acupuncture is very effective for fibromyalgia…"

8. Public Comments

CMS received two public comments regarding the use of acupuncture for the treatment of fibromyalgia. Both comments were in favor of a national Medicare coverage policy.

9. Future Research

The state of acupuncture research remains investigational. Adequate study designs, such as large multicenter RCTs with three arms including real acupuncture, sham acupuncture and placebo, are still being developed and tested. Evidence to determine potential utility of acupuncture for fibromyalgia may be obtained from RCTs including measurements of pain and quality of life using validated instruments, larger sample sizes and long-term follow-up.

Ongoing Clinical Trials

Issues regarding the use of acupuncture as a therapeutic modality for fibromyalgia that are being examined include:

- Optimal number of acupuncture points
- Duration and frequency of treatment
- Independent and synergistic effects of needle placement on efficacy
- Appropriate research design and control strategies

The National Center for Complementary and Alternative Medicine (NCCAM) is one of the 27 institutes and centers that make up the National Institutes of Health (NIH). Studies of acupuncture for fibromyalgia are now being sponsored by NCCAM and NIH. Four pilot studies are presently funded and can be accessed by entering “acupuncture” and “fibromyalgia” in the searchable database of federally funded biomedical research projects provided by the Computer Retrieval of Information on Scientific Projects (CRISP) at http://crisp.cit.nih.gov/.

Grant #5R01AT000004-02 “Pilot Study of Acupuncture in Fibromyalgia” is examining numerous issues regarding the use of acupuncture as a therapeutic modality in fibromyalgia, such that a full scale randomized controlled trial (RCT) can be performed. Issues under investigation include: 1) optimal duration and frequency of acupuncture treatment, 2) independent and synergistic effects of needle placement and needle stimulation on efficacy, and 3) appropriate control strategies. The four arms of the trial will include: 1) active site with stimulation, 2) active site without stimulation, 3) sham site with stimulation, and 4) sham site without stimulation. Secondary goals of the study are to collect pilot data on the mechanism, safety, and cost-effectiveness of acupuncture in fibromyalgia, and to determine the optimal outcome measures, for a full-scale RCT.

Male and female subjects from 18 – 65 years of age were eligible for this pilot study, but recruitment of patients has ended. Subjects must have met ACR criteria for fibromyalgia, had continued widespread pain for more than 50% of days, and been willing to limit the introduction of any new medications or treatment modalities for control of fibromyalgia symptoms during the 13 weeks of active treatment. Excluded were subjects with a knowledge of acupuncture sufficient to prevent blinding, presence of a known coagulation abnormality that would prevent safe use of acupuncture, presence of a concurrent autoimmune or inflammatory disease that causes pain, routine daily use of narcotic analgesics or history of substance abuse, participation in other concurrent therapeutic trials, disability insurance payments, or ongoing litigation related to fibromyalgia. The study began at Georgetown University in September 1999 and is scheduled to end July 2003.

Grant #5R01AT000003-02 “Efficacy of Acupuncture in the Treatment of Fibromyalgia” began at the University of Washington in September 1999 and is scheduled to end July 2003. An abstract for this project is not currently available on the CRISP online database.

Grant #1K01AT001111-01 “Mechanisms of Acupuncture Analgesia” focuses on determining the neurobiological mechanisms of acupuncture analgesia (the relief of pain) in patients with fibromyalgia. During the first two years, the study will: 1) establish the ideal conditions for acupuncture induced analgesia, and 2) begin to elucidate the mechanisms of acupuncture induced analgesia by using both psychophysical and functional magnetic resonance imaging experiments. The project began at University of Michigan in September 2002 and is scheduled to end July 2007.

Grant #5P50AT000084-04 deals with the establishment of a specialized center for research in complementary and alternative medicine (CAM) focusing on arthritis and related diseases. “The Center for Alternative Medicine Evaluation and Research in Arthritis” will support a multi-disciplinary team of researchers and develop institutional and regional collaborations to conduct clinical and basic research. Issues to be explored include: 1) the effectiveness of mind/body therapies for fibromyalgia; and 2) the mechanism of action and effects of electroacupuncture on persistent pain and inflammation. The project began at the University of Maryland Baltimore in September 1999 and is scheduled to end July 2004.

Ongoing Reviews

On October 21, 2002, NCCAM and 16 Federal co-sponsors announced that the Institute of Medicine (IOM), component of the National Academies, would study the scientific and policy implications of the use of complementary and alternative medicine (CAM) by the American public. NCCAM, the primary sponsor of the study, is the Federal Government's lead agency for scientific research on CAM. The National Academies is a private, nonprofit, non- governmental institution created by a congressional charter to be an advisory body for the nation on scientific and technological matters. The IOM draws upon volunteer panels of experts to examine policy matters regarding the public's health.

The IOM will assemble a panel of approximately 16 experts from a broad range of CAM and conventional disciplines, such as behavioral medicine, internal medicine, nursing, epidemiology, pharmacology, health care research and administration, and education. During the course of the study, the IOM panel will assess research findings, hold workshops, and invite speakers to address the panel, among other activities, in order to: 1) provide a comprehensive overview of the use of CAM therapies by the American public; 2) identify significant scientific and policy issues related to CAM research, regulation, integration, training, and certification; and 3) develop a conceptual framework to help guide decision-making on these issues and questions.

The IOM study committee will not be conducting new surveys of CAM use by the American public, nor will it assess the efficacy or safety of CAM products. Rather, the IOM panel will analyze existing data and will develop conceptual frameworks to guide decision-making on key issues and questions. Specifically, the Institute of Medicine (IOM) has been asked to form a committee to identify major scientific and policy issues in the following four areas:

- CAM research challenges and needs

- CAM regulation in the United States and other countries
- Interface and integration of CAM with conventional medicine
- Training and certification questions

The answers to these questions, and the information generated by the IOM panel of leading scholars drawn from both conventional medicine and CAM, will complement the WHCCAMP recommendations described just above in the previous section of this decision memorandum. The IOM project description, anticipated committee membership, upcoming meetings and additional information (as it becomes available) can be accessed by joining the CAM list serve or entering the keyword "CAM" on the IOM's website.[23]

AHRQ, along with many other national organizations, is co-sponsoring the IOM study on acupuncture. Information about the IOM is available at http://www.iom.edu and about the National Academies at http://www.nationalacademies.org. NCCAM is likewise dedicated to exploring CAM practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professionals. Additional information about the NCCAM is available at http://www.nccam.nih.gov.

VIII. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act § 1869(f)(1)(B). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." § 1862(a)(1)(A).

1. Strengths and Weaknesses of the Evidence

This decision memorandum focuses on: "Is there evidence of adequate methodological quality to conclude that the use of acupuncture significantly and reliably reduces pain in Medicare patients with fibromyalgia?"

Although there have been anecdotal reports of the efficacy of acupuncture for fibromyalgia, there has only been one consistently commented upon RCT.[24] There are, however, methodological problems with Deluze, *et al.*'s (1992) study that limit the interpretation of its data, and there are conflicting conclusions regarding its methodological quality.[25,26]

Berman, *et al.* (1999) described Deluze's RCT as a high quality study of electroacupuncture for fibromyalgia, yet concluded that further randomized trials are needed to provide more robust data on effectiveness. Berman's group also enumerated three important questions that were raised but not answered by existing studies: 1) duration of benefit; 2) optimal electrical frequencies; and 3) any possible synergy with antidepressant medication. In that same order Berman, *et al.* noted that: 1) Deluze's study did not report long-term follow-up; 2) choice of single or combined electrical frequencies remains an important hypothesis to test in future studies; and 3) small sample size, high dropout rate and lack of between-group analysis precluded answering whether acupuncture synergistically works with antidepressant medication.

Both the 2001 NHS and 2002 AHFMR reports systematically evaluated Berman, *et al.'s* (1999) review. Contrary to that reported by Berman's group, the NHS report concluded that there was only a limited amount of positive evidence and that further research was needed for acupuncture for fibromyalgia.[27]

The 2002 AHFMR assessment noted that Berman, *et al's* (1999) review used the Jadad scale to rate the methodological quality of the studies. "They did not, however, identify the style (e.g. classical TCM or formula acupuncture), appropriateness of treatment, or the qualifications of the acupuncture practitioner. The authors based their conclusions on one high quality RCT, which found significant improvement in both subjective and objective pain measures compared to sham acupuncture but the duration of benefit was unknown. A few patients had worsening of symptoms during the treatment with acupuncture…." In Table 2 of the AHFMR report, it was also noted that even though a study's [Deluze, *et al*.'s] "high score" was mentioned in Berman's results, those authors did not report the quality scores, just a summary of the data extraction.[28]

The 2002 Bandolier analysis (a tertiary review of reviews) of Deluze, *et al's* (1992) study further emphasized that co-interventions had not been avoided, randomization had not provided similar groups, duration of benefit was unknown, and there were patients randomized to both the real and sham electroacupuncture treatment groups who had worsening of symptoms.[29]

Sim and Adams (2002) likewise criticized Deluze's study. Rebutting Berman, *et al.*'s (1999) contention that only Deluze's study is of high methodological quality on the Jadad scale[30], Deluze's study scored only 50.5 on a 100-point quality scale in Sim and Adams own review. Co-interventions were not avoided in Deluze's study, and the continuation of patients' usual physical therapy and medications were said to have possibly confounded the results. Sim and Adams concluded that, despite the encouraging findings presented by Deluze and colleagues, further randomized studies of acupuncture for fibromyalgia are needed.[31]

Also of concern is the association of positive patient expectations with placebo responses. That is to say, acupuncture's effect may be predominantly mediated by non-specific placebo effects produced by the therapeutic encounter itself, rather than specific effects produced by appropriate acupuncture needling. Placebo effects could include the amount of physical contact and relaxation experienced by the patient, the personality and perceived empathy of the acupuncturist, as well as patient expectations about the likely value of acupuncture. The nonspecific and specific effects of real and sham acupuncture procedures remain unclear.[32]

2. Conclusion

In summary, CMS concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with fibromyalgia. Deluze's three-week RCT was not long enough to draw conclusions about electroacupuncture's impact on health outcomes for patients with chronic fibromyalgia, and generalizations from Deluze's electrically stimulated acupuncture study cannot be made to manually stimulated needling or the many varieties and styles of non-needling acupuncture techniques. There is similarly no study evaluating the best protocol or type of acupuncture for fibromyalgia. Studies have also not yet been properly designed or controlled to adequately demonstrate whether real acupuncture with standardized needling or non-needling techniques works better than placebo control or sham acupuncture, standard medical therapy or no therapy. Such study design flaws presently prohibit determination of acupuncture's utility and make the evidence inadequate to determine that acupuncture for fibromyalgia improves health outcomes. CMS, therefore, concludes that this intervention is not reasonable and necessary.

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1 Aaron*, et al*. 2001

2 Hudson, *et al.* 1992

3 http://www.rheumatology.org/research/classification/fibro.html

4 Wolfe, *et al.* 1990

5 http://www.rheumatology.org/publications/primarycare/number1/hrh0004-98.html

6 *De qi* is a sensation of numbness, tingling, electrical sensation, fullness, distension, soreness, warmth or itching felt by a patient around an acupuncture point. Whether it is necessary to elicit *de qi* to render a treatment effective remains controversial among acupuncturists. Alberta Heritage Foundation for Medical Research (AHFMR) Health Technology Assessment 2002

7 Microcurrent stimulation and electroacupuncture involve introduction of an electrical current to the inserted needles at various frequencies. The Chinese term *zhenjiu*, referencing both acupuncture and moxibustion, involves warming of the needles by burning the dried herb *Artemisia vulgaris* (mugwort) over the acupuncture point. Staple acupuncture involves application of a metal staple for a prolonged period of time to an acupuncture point. Cupping acupuncture involves application of vacuum force to acupuncture points. Acupressure (without needles) involves the stimulation of an acupuncture point manually with pressure with the intention of stimulating *qi* flow. Laser acupuncture involves stimulation by a laser beam directed at the acupuncture point. Fire needling involves inserting red-hot needles at acupuncture points. AHFMR Health Technology Assessment 2002

8 Eisenberg, *et al.* 2002

9 ibid.

10 http://www.abms.org/links.asp

11 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=880.5580

12 http://www.fda.gov/bbs/topics/ANSWERS/ANS00722.html

13 AHFMR Health Technology Assessment 2002

14 Gallagher, *et al.* 2001

15 Jadad, *et al.* 1996

16 United Kingdom NHS Review 2001

17 AHFMR Health Technology Assessment 2002

18 Berman, *et al.* 1999

19 Deluze, *et al.* 1992

20 Berman, *et al.* 2000

21 http://www.jr2.ox.ac.uk/bandolier/band90/b90-3.html

22 Deluze, *et al.* 1992

23 http://www.iom.edu/iom/iomhome.nsf/SearchView/$SearchForm?SearchView

24 Deluze, *et al.* 1992

25 Berman, *et al.* 1999

26 Sim, *et al.* 2002

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30 Berman, *et al*. 1999

31 Sim and Adams 2002

32 AHFMR Health Technology Assessment 2002

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